**GUTHRIE** *Foundation*

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Dockets Management Branch HFA-305
Food and Drug Administration
5630 Fishers Lane, Rm 1061
Rockville, MD 20852

I have recently reviewed the proposed rules regarding medical gloves in the Federal Register Vol 64, No 146 July 30, 21 CFR Parts 801, 878, and 880 Docket No 98N-0313 RIN 0910-AB74.

General comments:

I would like to thank the FDA for taking a stand on issues relating to the multiple concerns of adverse health effects associated with powder from the surface of medical gloves. I wish that FDA would take a firmer stand and support a ban on all powdered gloves. I understand the concerns for manufacturing considerations, but having worked with manufacturers for nearly 10 yrs now, I think undue weight has been given to their considerations. A safe healthcare environment is of utmost importance and powdered gloves are not safe.

Comments on specific points requested by FDA.

1. *Time frame*: In conversations with independent manufacturing experts from Malaysia, they were of the opinion that 18 months of time would be required for a factory to completely convert to powder free production, if the factory had no prior knowledge of powder-free technology. Since most manufacturers are well aware of the trends towards powder-free gloves and most already produce powder-free gloves, a 12 month time frame is more than adequate.

2. *Powder limit of 120 (regardless of size).* If we can not ban powdered gloves, then the next best thing is to limit the amount of powder, but 120 mg of powder is still a significant amount of powder. Although I believe all gloves should be powder-free, 120 mg or ~12 mg/dm$^2$ is the absolute maximum amount of powder that should be considered. Having said that, it should be required on a per dm$^2$ or per gram basis rather than a per glove basis. The requirements of powder levels on a per glove basis produces different manufacturing requirements for different sized gloves and that should be avoided.

3. *Comments on feasibility and desirability that additional labeling require primary ingredients in glove powder on glove label;* I think the type of donning and mold release powder should be required on the label. Both powders become distributed on both patient contact and wearer contact surfaces and therefore are aerosilized.

98N-0313

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4. *Recommending no more that 2 mg powder per glove (regardless of size)*: Again I support a low limit of powder level on powder-free gloves but it should be expressed on a per $dm^2$ or per gm basis. 2 mg is a reasonable amount on powder-free gloves.

*Impact of powder-limits on barrier properties and shelf life.* While improper chlorination may have a negative impact on barrier properties and shelf life, if properly done it does not have a deliterious effect, thus barrier properties can be a indicator of proper chlorination. Reducing shelf life to a safe and reasonable time period would prevent stock piling of gloves and ensure fresher, better products.

5. *Future requirement that all surgeon's and exam gloves be powder free.* I don't think this should be a future requirement, but a present one. As noted in your proposed rules, there is significant scientific evidence to indicate that glove powder causes many many adverse health problems. Powders should be banned now. If a ban can not be a present requirement, a "phase in" period could be required.

One thing that was not included in the FDA's cost estimates were healthcare costs due to re-operations. The foreign body reactions often require re-operation for adhesiolysis. In 1988, in-patient costs of re-operation for lower abdominal adhesiolysis alone was estimated at 1.17 billion annually in the United States (Ray et al). Of factors which cause re-operations, foreign body granulomas are the primary cause. Starch granuloma was found to cause a minimum of 10% of the adhesions following surgery less that 6 months old (Jeekel). Taken together one might estimate that a minimum or $117 million are spent annually for adhesiolysis due to glove donning powders. These and potential cost considerations of other adverse effects of glove powder such as increased likelihood of post operative infection, increased scarring, potential spread of bacteria and endotoxin, etc. make it imperative that glove powders be banned.

Ray, NF, Larsen JW, Stillman RJ, Jacobs RJ. Economic impact of hospitalizations for lower abdominal adhesiolysis in the Untied States in 1988. Surg Gynocol Obstet 1993; 176, 271-276.

Jeekel H, Cost implications of adhesions as highlighted in a European study. Eur J Surg Suppl 1997; 579: 43-45.

6. *Restricting sale of powdered gloves:* Absolutely, better yet ban the use of powdered gloves.

7. *Recommending an upper limit of 1200 µg (regardless of size).* I think the protein limits (both low and high) need to be a requirement, but must be expressed on a per $dm^2$ or a per gm basis. There is a big problem of requiring limits on a per glove basis (although it is better for the consumer).

As one of the oldest and most established laboratories testing protein levels on gloves, we are keenly aware of these problems. In fact, given the wide range of glove weight, size and thickness, and the poor sensitivity and specificity of the D5712 Lowry test, few glove manufacturers (even the better quality ones) will be able to make a low protein claim let alone meet the 1200 µg/glove level. With the 300 µg/glove cut off for low protein, all but the smallest or thinnest gloves will be excluded from the claim. Our lab has a fairly low reporting limit for the D5712 assay of 8.3 µg/ml. Using the recommended 5 to 1 extraction ratio of D5712-99, this works out to be a 41.5 µg/gm reporting limit. This means that if a glove weighs more than 7.2 grams (a majority of all gloves), the Lowry assay is not capable of determining a protein level of less than 300 µg per glove. For example, 7.2 gm x 41.5 µg/gm = 300 µg total. If the glove weighs more than 7.2, for example 8 gm, then 8 x 41.5 = 332 µg and therefore a manufacturer could not make the low protein claim. With a lower extraction ratio such as 3:1 the situation is a little better in that the detection limit becomes 24.9 µg/gm. At that level gloves less than 12 gm can be analyzed.

Unfortunately to level the playing field, proteins should be expressed on a per gm or per $dm^2$ basis. Using a per $dm^2$ basis, the ASTM standard must be changed so that products are also extracted on a per $dm^2$ basis rather than a per gram basis. The extraction ratio must also be minimized. To extract gloves on a per gram basis, and express data on a per $dm^2$ basis is not

desirable. Difficulties arise since the conversion of μg/gm to μg/dm$^2$ depends on the thickness of the gloves. In a recent survey of different glove brands from one manufacturer we found a conversion factor for μg/gm to μg/dm$^2$ ranging from 0.8 to 1.7.

Another consideration about making limits on protein levels is that with the ELISA method nearing completion, some provision should be made in the regulations for other limits based on that test. If 50 μg/gm and 200 μg/gm become fixed limits, transition to the new test will be difficult.

To summarize, I think there should be a 200 μg/dm$^2$ limit as the upper limit and 50 μg/dm$^2$ as a low protein claim, but the ASTM Lowry would have to be modified. The limits should not be on a per glove basis but rather a μg/gm or μg/dm$^2$ basis, and provision should be made for the different levels based on the newer test method.

8. *FDA objectives are to reduce adverse health effects from allergic and foreign body reactions by controlling protein and powder levels.* I think these are appropriate and desirable objectives, but to achieve these objectives powder should be eliminated not just regulated.

9. *Recommended or required limits.* The limits should be required. If they are only recommendations don't bother going through the process. We know that the recommendations would not be treated seriously but requirements would be.

10. *Shelf life.* I think a shelf life is important and is necessary, but work will be required to establish proper parameters for determining shelf life. Again shelf life would serve the purpose to better ensure gloves free from barrier defects would be used.

11. S*pecial air handling for powdered glove use.* I think this is totally un-necessary since the powder should be eliminated. If it were, then special regulations for air handling would be obsolete. Special air handling equipment would be considerably more expensive that a switch to powder free gloves.

12. *Exemptions or variances from labeling requirements* should probably be allowed for a limited period to make transition to the new regulations smooth and reasonable.

Thank you for the opportunity to comment on these proposed regulations. For the safety of health care workers and our patients, please implement these changes as soon as possible.

Sincerely;

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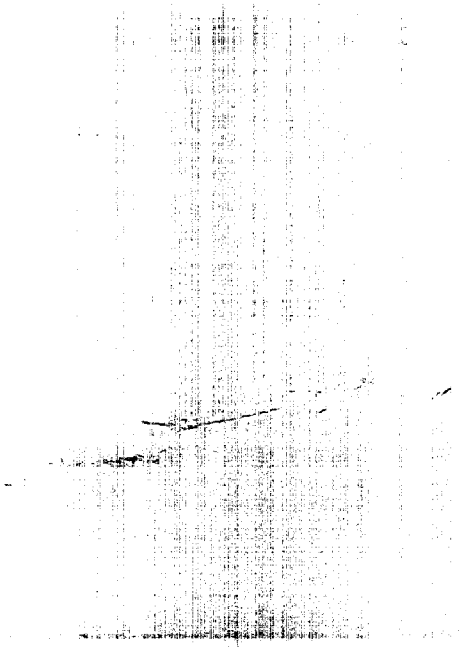

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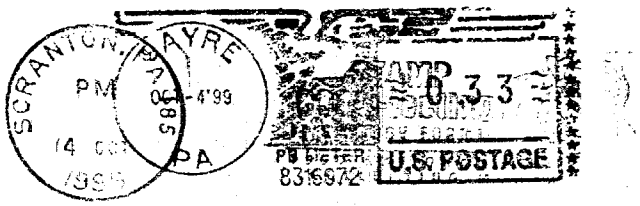


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